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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,876	03/15/2004	Sharen A. Godwin	5714-001	1938

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EXAMINER	
PASS, NATALIE	

ART UNIT	PAPER NUMBER
3686	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,876	GODWIN ET AL.	
	Examiner	Art Unit	
	Natalie A. Pass	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *18 August 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 15 March 2004. Claims 1-20 are pending. The Information Disclosure Statement filed 18 August 2004 has been entered and considered.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-20 are rejected under 35 U.S.C. §101.

A) As per claims 1-20, these appear to be directed toward a method or process of identifying prospective clinical trial participants. Based on Supreme Court precedent, and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr,* 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson,* 409 U.S. 63, 70 (1972); *Cochrane v. Deener,* 94 U.S. 780,787-88 (1876).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

In the instant application, Appellant's method steps fail the first prong of the new Federal Circuit decision since they are not required to be tied to another statutory class and can be performed without the use of a particular apparatus. In particular, Applicant's claims do not recite who or what is performing the method steps. Furthermore, the method steps fail to unambiguously require transformation of underlying subject matter to a different state or thing. The mere manipulation and production of non-functional descriptive material (i.e., "patient identifiers") is not a transformation because a patient identifier is not statutory subject matter. Thus, claims 1-20 are non-statutory since they are not requisitely tied to another statutory class and they do not requisitely transform underlying subject matter to a different state or thing.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7, 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Independent claim 1 recites a preamble followed by a listing of method steps, but fails to contain a transitional phrase, which is required to define the scope of the claim. For the purpose of applying art, Examiner assumes the preamble of the claim to read "… [...] ... identified by non-personal identifiers, comprising:" (see MPEP 2111.03). Correction is required.

B) Claims 2-7 incorporate the features of independent claim 1, through dependency, and are also rejected. See *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990).

C) Claims 14-15 recite "said database" in line 1, respectively. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-9, 11-15 are rejected under 35 U.S.C. 102 (b) as being anticipated by Davies et al., U.S. Patent Application Publication Number 2003/0046114.

(A) As per claim 1, Davies teaches a method of acquiring information relating to potential clinical trial participants meeting predetermined criteria using a data source that includes the dictation records of at least one healthcare professional containing information relating to the medical conditions of a plurality of patients identified by non-personal identifiers;

a) selecting the identifiers of patients in said data source that potentially meet said criteria (Davies; paragraphs [0018], [0023]- [0024], [0032], [0064]-[0065]); and

b) transmitting said patient identifiers to said healthcare professional to enable said healthcare professional to contact said patients regarding said clinical trial (Davies; paragraphs [0053]- [0055]).

(B) As per claims 2-7, Davies teaches a method as analyzed and discussed in claim 1 above

wherein said data source is a data stream generated during transcription of dictated records (Davies; paragraph [0098]);

wherein said dictation records are transcribed dictation records (Davies; paragraphs [0022]-[0025], [0053]-[0054], [0098]);

wherein each transcribed dictation record is compared against said criteria immediately following transcription (Davies; paragraphs [0024], [0032], [0053]-[0054], [0069]);

wherein said healthcare professional is selected from the group consisting of physicians, dentists, chiropractors, hospitals and clinics (Davies; paragraph [0053]);

wherein said predetermined criteria include at least one criterion selected from the group consisting of disease state, ICD code, and patient complaint (Davies; paragraphs [0011], [0018], [0032]); and

wherein said data source includes at least one additional source of information relating to the medical conditions of said patients selected from the group consisting of billing records, laboratory records, and admission records, and demographic information (Davies; paragraphs [0023]-[0025], [0052]).

(C) As per claim 8, Davies teaches a method of identifying prospective clinical trial participants meeting predetermined criteria using a data source including the dictation records of at least one healthcare professional containing information relating to the medical conditions of a plurality of patients identified by non-personal identifiers comprising:

a) receiving predetermined criteria from a clinical researcher (Davies; Abstract, paragraphs [0013]-[0015], [0063]);

b) preparing a search query based on said predetermined criteria (Davies; Abstract, paragraphs [0013]-[0015], [0063]);

c) selecting non-personal identifiers of patients in said data source that potentially meet said criteria (Davies; paragraph [0086]); and

d) transmitting said identifiers to said healthcare professional to enable said healthcare professional to contact patients who would want to consider participating in said trial (Davies; paragraphs [0032], [0053]- [0055]).

(D) As per claims 9, 11-15, Davies teaches a method as analyzed and discussed in claim 8 above

wherein said data source is a data stream generated during transcription of dictated records (Davies; paragraph [0098]);

wherein said dictation records are transcribed dictation records (Davies; paragraphs [0022]-[0025], [0053]-[0054], [0098]);

wherein said healthcare professional is selected from the group consisting of physicians, dentists, chiropractors, hospitals and clinics (Davies; paragraph [0053]);

wherein said predetermined criteria include at least one criterion selected from the group consisting of disease state, ICD-9 code and patient complaint (Davies; paragraphs [0011], [0018], [0032]);

wherein said database includes at least one additional source of information relating to the medical conditions of said patients selected from the group consisting of billing records, laboratory records, and admission records (Davies; paragraphs [0023]-[0025], [0052]); and

wherein said database includes the geographical locations of said patients (Davies; paragraph [0015]).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 10, 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al., U.S. Patent Application Publication Number 2003/0046114, as applied to claim 8 above, and further in view of McAlindon, et al., U.S. Patent Number 7251609.

(A) As per claim 10, Davies teaches a method as analyzed and discussed in claim 8 above.

Davies fails to explicitly disclose a method

wherein said non-personal identifier is an alphanumeric identifier.

However, the above features are well-known in the art, as evidenced by McAlindon.

In particular, McAlindon teaches a method

wherein said non-personal identifier is an alphanumeric identifier (McAlindon; column 10, lines 51-57, column 25, lines 1-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Davies to include these limitations, as taught by McAlindon, with the motivations of "ensur[ing] security of trial participants' data" and "so that the

participant's actual name, or other identifying features, will not be present in the trial database" (McAlindon; column 25, lines 1-11).

(B) As per claim 16, Davies teaches a method of identifying prospective participants for a clinical trial who meet participant criteria from a data stream of individual patient records created during transcription of the dictation of at least one healthcare professional containing information relating to the medical conditions of a plurality of patients identified by non-personal identifiers comprising:

a) preparing a search query based on said predetermined criteria (Davies; Abstract, paragraphs [0013]-[0015], [0063]);

b) comparing each of said records against said query immediately following creation of the record (Davies; paragraphs [0024], [0032], [0053]-[0054], [0069]);

c) selecting non-personal identifiers of patients in said data stream that potentially meet said criteria (Davies; paragraphs [0018], [0023]- [0024], [0032], [0064]-[0065], [0086], [0098]); and

d) transmitting said non-personal identifiers of selected patients to said healthcare professional for use by the healthcare professional in obtaining contact authorization from selected patients (Davies; paragraphs [0053]- [0055], [0086]).

Davies fails to explicitly disclose

e) receiving the names of patients who have consented to be interview regarding the clinical trial from said healthcare professional; and

f) contacting patients whose names are received from said healthcare professional.

However, the above features are well-known in the art, as evidenced by McAlindon.

In particular, McAlindon teaches

e) receiving the names of patients who have consented to be interview regarding the clinical trial from said healthcare professional (McAlindon; column 4, lines 26-47); and

f) contacting patients whose names are received from said healthcare professional (McAlindon; column 4, lines 26-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Davies to include these limitations, as taught by McAlindon, with the motivations of "recruiting and screening for candidates who are eligible to participate in a clinical trial" (McAlindon; Abstract).

(C) As per claims 17- 20, Davies and McAlindon teach a method as analyzed and discussed in claim 16 above

wherein said query is based on information provided by a clinical researcher (Davies; Abstract, paragraphs [0013]-[0015], [0063]), said method further including the step of providing the identification of authorizing patients to said researcher (Davies; paragraphs [0032], [0053]-[0055], [0063], [0092]);

wherein said data stream includes the geographical location of said patients (Davies; paragraph [0015], [0023]-[0024], [0098]);

wherein said data stream includes dictation records of a plurality of "users" (reads on "healthcare professionals") (Davies; paragraphs [0025], [0065]), the identifier of each selected patient being transmitted to the healthcare professional originating the record relating to the medical conditions of the selected patient (Davies; paragraphs [0032], [0053]- [0055]); and

wherein said data stream is accessed after transcription (Davies; paragraphs [0023]-[0024], [0032], [0053]-[0054], [0069], [0086], [0098]).

The motivations for combining the respective teachings of Davies and McAlindon are as given in the rejection of claim16 above, and incorporated herein.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied references Klein et al., U.S. Patent Application Publication Number 2002/0194026, Henderson et al., U.S. Patent Application Publication Number 2003/0236683, Rishell et al., U.S. Patent Application Publication Number 2007/0067210, Deakter, U.S. Patent Application Publication Number 2004/0093238, Buonocore et al., U.S. Patent Application Publication Number 2004/0010418, Krishnan et al., U.S. Patent Application Publication Number 2005/0234740, Chintalapati et al., U.S. Patent Application Publication Number 2003/0046350, Rosenthal et al., U.S. Patent Application Publication Number 2002/0133502, and Rao et al., U.S. Patent Application Publication Number 2003/0125988 teach the environment of identifying clinical trial participants.

11. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington D.C. 20231

or faxed to: **(571) 273-8300**.

For informal or draft communications, please label "PROPOSED" or "DRAFT" on the front page of the communication and do NOT sign the communication.

After Final communications should be labeled "Box AF."

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/N. A. P./
Examiner, Art Unit 3626
March 5, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686